CANNABIS LICENSING APPLICATION GUIDE

Application Requirements and Process to Become a Licence Holder under the *Cannabis Act* and its Regulations

Government of Canada / Gouvernement du Canada

Canada

The *Cannabis Act* establishes that an application for a licence must be filed with the Minister of Health in the form and manner specified by the Minister and must include the information required by the Minister. This guide sets out the application process including the form and manner for submitting an application for a licence and the information that is required to be submitted. In accordance with the *Cannabis Act*, the Minister may also request any additional information that pertains to the information contained in an application and that is necessary to consider it. It is important to note that in the case where any information required to be submitted is not provided, the Minister may refuse to consider an application.

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1.0 Purpose

This document (the "Guide") provides information on the application requirements to obtain a licence from Health Canada under the *Cannabis Act* and its Regulations.

2.0 Background

The *Cannabis Act* and its Regulations provide, among other things, the framework for legal access to cannabis and control and regulate its production, distribution and sale.

The oversight of the cannabis supply chain is a shared responsibility across federal and provincial and territorial governments, municipalities, industry and other stakeholders. One of Health Canada's responsibilities is to provide the licensing and oversight framework for legal production of cannabis. Under this framework, a person is required to obtain a licence issued by Health Canada in order to conduct various activities with cannabis. Applicants and licence holders are responsible for compliance with the *Cannabis Act* and its Regulations as well as compliance with other applicable federal, provincial and territorial legislation and municipal by-laws.

The *Cannabis Act* establishes that an application for a licence must be submitted to Health Canada in the form and manner specified by the Minister of Health[1] and must include the information required by the Minister. This guide sets out the application process including the form and manner for submitting an application for a licence and the information that is required.

Health Canada publishes other guidance documents and information on its website that may be used in conjunction with this document to assist applicants in preparing their applications. In order to maintain consistency and transparency, this guide, as well as other guidance documents and information, will be updated, as required, to reflect changes to policies and/or operations.

3.0 Scope

This document provides guidance to anyone wishing to apply for a licence ("the applicant") under the *Cannabis Act* and its Regulations to conduct activities in relation to the following classes and subclasses of licences:

- Cultivation (including licences for micro- and standard cultivation or nursery)
- Processing (including licences for micro- or standard processing)

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[1] Throughout this guide, there are references to actions that would be taken by the Minister of Health under the *Cannabis Act* and its Regulations, often in the context of decision-making. In many cases, it is anticipated that the decision-making function would not be exercised personally by the Minister, but instead by an official in the Department of Health who is in a capacity appropriate to making the decision. This would be consistent with ministerial decision-making practices in many other contexts, and in accordance with the common law and the *Interpretation Act*.

- Sale for medical purposes
- Analytical testing
- Research

The following activities are not addressed in this guide:

- Application for an industrial hemp licence
- Application for a cannabis drug licence
- Test kit manufacturing
- Post-licensing applications including licence amendments and renewals, notifications, and applications for import or export permits
- Reporting including inventory, recall, and information related to promotions and adverse reaction reporting
- Applications for registration by an individual to access cannabis for medical purposes as outlined in Part 14 of the *Cannabis Regulations*
- Any other items identified as regulatory requirements outside the scope of these specific application requirements

For more information on requirements associated with the activities that are not addressed in this guide, applicants may refer to the *Cannabis Act* and its Regulations, additional guidance published on the Health Canada website, or contact Health Canada as outlined in section 8 of this guide.

In addition, this guide does not include information on additional licensing requirements that may be required by the Canada Revenue Agency or provinces and territories.

Of particular note, Health Canada has established a national cannabis tracking system, referred to as the Cannabis Tracking and Licensing System (CTLS), to enable the tracking of high-level movements of cannabis and to help prevent diversion from and inversion into the regulated supply chain. The system is also used by applicants to apply to Health Canada for a cannabis licence. Applicants should be familiar with the use of this system and should refer to the CTLS User Guide for more information, available upon request from cannabis@canada.ca. This guide is based on the CTLS release 1.1.

Supplemental information, including on cost recovery fees, will be provided by Health Canada when applicable.

In cases of discrepancy between the CTLS and the *Cannabis Regulations* or guidance, or if the use of the CTLS is not feasible, Health Canada should be contacted for further information. The *Cannabis Regulations* and this guide should be referred to for the established requirements and terminology.

4.0 Definitions and Abbreviations

4.1 Definitions

The *Cannabis Act* and its Regulations should be referred to for definitions. The definitions in this section are provided for ease of reference.

Cannabis Tracking and Licensing System (CTLS): The name of the national cannabis tracking system as referred to in the *Cannabis Act*, established and maintained by Health Canada to enable tracking of high-level movements of cannabis and to help prevent diversion from and inversion into the regulated supply chain. It is also the system that applicants should use to apply to Health Canada for a cannabis licence.

Key investor: As defined in the *Cannabis Regulations*, means, in respect of the holder of a licence, a person that exercises, or is in a position to exercise, direct or indirect control over the holder by virtue of:
(a) having provided money, goods or services directly or indirectly to the holder; or
(b) holding an ownership interest or other right or interest in, or in respect of, a business operated by the holder or, if the holder is an organization, in or in respect of the organization.

Refer to Appendix I: Key Investors, for more information.

Local government: As defined in the *Cannabis Regulations*, includes:
(a) an incorporated city, metropolitan area, town, village or other municipality;
(b) an authority responsible for delivering municipal services that are related to the activities to be conducted under the licence to an unincorporated city, metropolitan area, town, village or other municipality;
(c) a band, as defined in subsection 2(1) of the *Indian Act*; or
(d) a First Nation, Métis or Inuit government that is party to a self-government or land claims agreement that is given effect by an Act of Parliament, or a First Nation, Métis or Inuit government established under a provincial Act.

Organizational security plan (OSP): An integrated plan that broadly outlines security information and operating procedures. It captures the security risk mitigation measures a licence holder takes to prevent, detect and respond to potential security incidents that could result in the diversion of cannabis to or from the illicit market.

Organizational chart: Visual representation of how authority, responsibility, and information are to flow within a formal organizational structure. It usually depicts different management functions (accounting, finance, human resources, marketing, production, research and development, etc.) and their subdivisions as boxes linked with lines along which decision making power travels downward and answerability travels upward. For the purposes of the application, the following two types of organizational charts are required:

Corporate organizational chart (for corporations, cooperatives and partners): Outlining the relationships of directors and officers (if a corporation or cooperative) or partners in a partnership, as well as any individuals, partnerships, cooperatives or corporations that directly control the licence.

Site organizational chart: This chart, which forms part of the organizational security plan, outlines the structure of the licence holder's organization showing the relationships of the management positions within it. For example, in addition to the officers, this chart must identify all persons who are primarily responsible for the following activities or have the following knowledge:

i. any product movement beyond minimal amounts
ii. setting operational procedures, including standard operating procedures
iii. sensitive security or business knowledge
iv. financial controls, including but not limited to the ability to enter into contracts for goods and services

Security clearance: As defined in the *Cannabis Regulations* means, except in paragraph 53(2)(g) of the Regulations, a security clearance granted by the Minister under section 67 of the Act and includes, for the purpose of paragraph 53(2)(e) of the Regulations, a security clearance granted under section 112 of the former *Access to Cannabis for Medical Purposes Regulations*.

Site: As defined in the *Cannabis Regulations* means, in respect of a holder of a licence, an area that is used exclusively by the holder that consists of at least one building or one part of a building. This typically includes:

Storage area: As defined in the Regulations means, in respect of a site set out in a licence, an area of the site where cannabis is stored.

Grow area: As defined in the Regulations means, in respect of a site set out in a licence, an area of the site where cannabis plants are cultivated, harvested or propagated.

Operations area: As defined in the Regulations means, in respect of a site set out in a licence, an area of the site — other than a storage area — where cannabis is present as a result of any activities conducted under the licence. It includes a grow area.

4.2 Abbreviations

CTLS Cannabis Tracking and Licensing System

FDA *Food and Drugs Act*

GPP	good production practices
OSP	organizational security plan
QAP	quality assurance person
RCMP	Royal Canadian Mounted Police
SOP	standard operating procedure

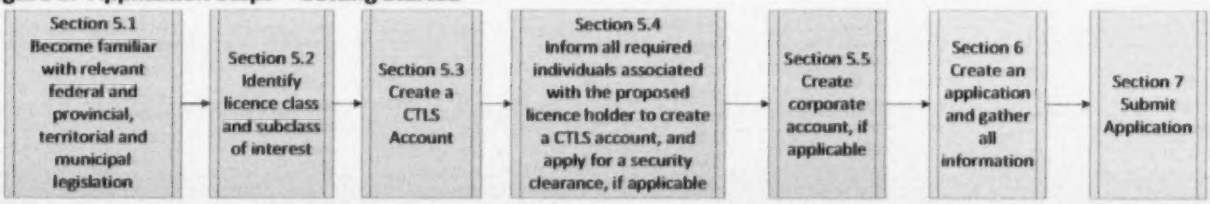
The following icons are used throughout this guide to highlight specific information of interest.

	Important: Key or cautionary information, in particular, around data required in the CTLS.
	Information: Highlights that there may be differences in requirements among licence classes (e.g., different requirements for analytical testing or research).
	Tip: Information that could be helpful.

5.0 Application Requirements: Getting Started

There are some specific actions that applicants should undertake when creating an application to Health Canada. The CTLS User Guide may be referred to for more information. The process flow outlined in Figure 1 provides a general summary.

Figure 1: Application Steps – Getting Started


Section 5.1 Become familiar with relevant federal and provincial, territorial and municipal legislation
Section 5.2 Identify licence class and subclass of interest
Section 5.3 Create a CTLS Account
Section 5.4 Inform all required individuals associated with the proposed licence holder to create a CTLS account, and apply for a security clearance, if applicable
Section 5.5 Create corporate account, if applicable
Section 6 Create an application and gather all information
Section 7 Submit Application

The applicant is not required to complete the application process in one session. The application may be started in CTLS and left in Draft status until the applicant is ready to submit it.

5.1 Knowledge areas

When applying for a licence, it is recommended that the applicant be familiar with the knowledge areas outlined below. This knowledge will help the applicant comply with the applicable requirements of the *Cannabis Act* and its Regulations as well as other federal and provincial or territorial legislation and regulations and/or municipal by-laws.

Table 1: Knowledge areas

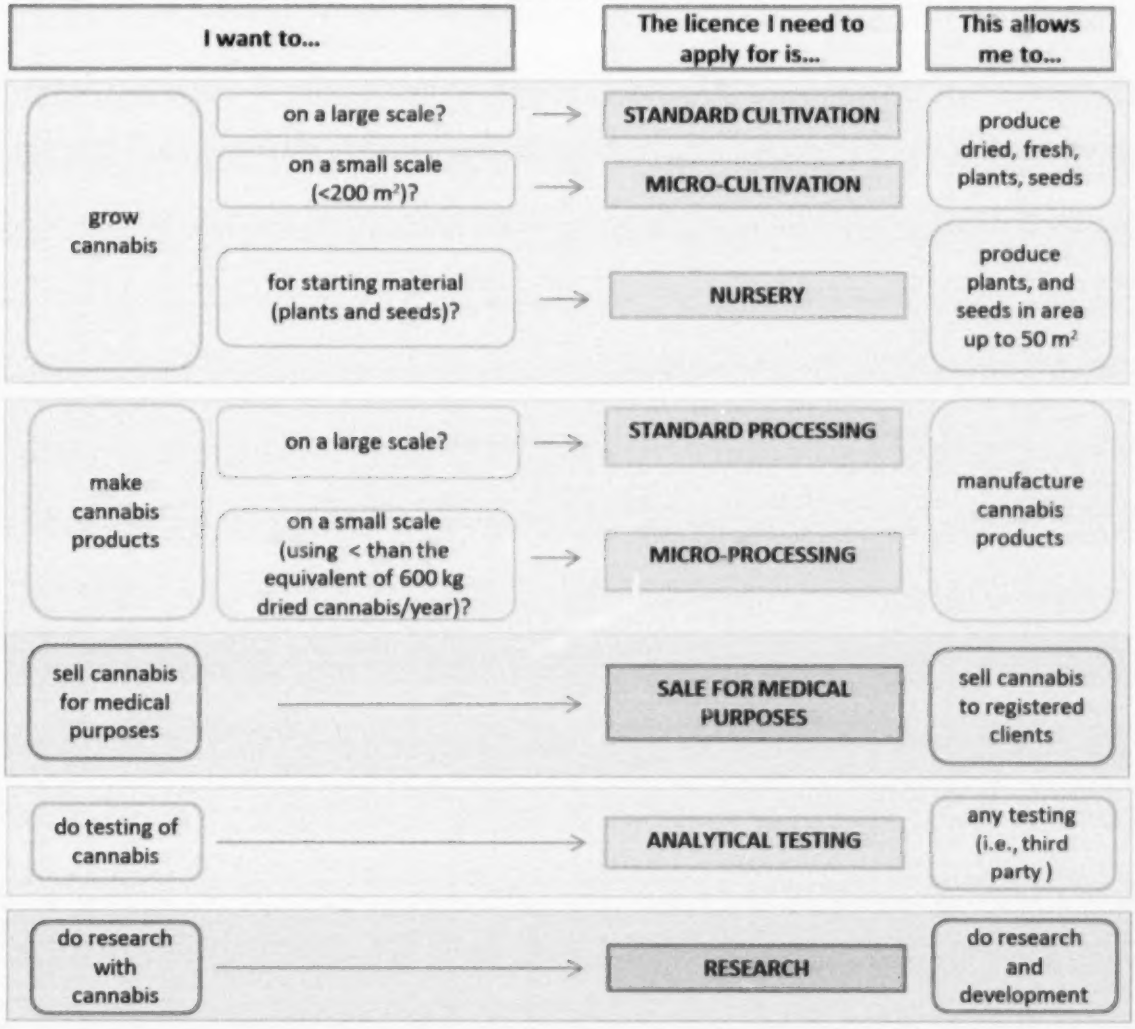
Key areas to be familiar with:	***Notes/References***
The *Cannabis Act* and its Regulations	Links may be found on Health Canada's website.
Other federal Acts and Regulations	Applicants are responsible for complying with applicable requirements of other Acts and Regulations such as the *Food and Drugs Act (FDA)*, the *Pest Control Products Act* and the *Fertilizer Act*, among others. For some research licences under the *Cannabis Act* as well as for cannabis drug licences, additional approvals are also required under the FDA and its Regulations.

The Canada Revenue Agency	Depending which activities will be conducted with cannabis, a cannabis licence under the *Excise Act* (2001) may also be required. For more information consult the Canada Revenue Agency at: www.canada.ca/cannabis-excise cannabis@cra-arc.gc.ca 1-866-330-3304
Provincial or territorial legislation and regulations, and ,municipal by-laws	It is the applicant's responsibility to comply with all applicable provincial or territorial laws and regulations (e.g., environmental laws) as well as municipal by-laws (e.g., zoning and building permits). The provincial or territorial or municipal body may be contacted for more information.
The Cannabis Tracking and Licensing System (CTLS)	Health Canada has established that the CTLS is the primary manner in which licence applications should be submitted. If this is not feasible, applicants may contact Health Canada for more guidance. Applicants should be familiar with the use of the CTLS. For more information, refer to the CTLS User Guide.
The licensing application requirements and process found in this guide	All applicable requirements need to be met in order for a licence to be issued.
Additional Health Canada guidance (e.g., including on promotions, packaging and labelling)	The *Cannabis Act* and its Regulations include requirements and prohibitions which go beyond the scope of this guide. This includes prohibitions around promotions and requirements for packaging and labelling, among others. It is the responsibility of the applicant to read and understand all the applicable requirements and any associated guidance found on the Health Canada website before applying.

5.2 Determine the type of licence to apply for

Applicants should be familiar with the classes and subclasses of licences to determine which class their activities of interest fall under. Requirements differ based on the licence class or subclass. Appendix B: Cannabis Classes and Subclasses of Licences should be referred to for details on each class and subclass, and Figure 2 can be used as a general reference.

Figure 2: Cannabis Classes and Subclasses of Licences


I want to...
The licence I need to apply for is...
This allows me to...
grow cannabis
on a large scale?
STANDARD CULTIVATION
on a small scale (<200 m²)?
MICRO-CULTIVATION
produce dried, fresh, plants, seeds
for starting material (plants and seeds)?
NURSERY
produce plants, and seeds in area up to 50 m²
make cannabis products
on a large scale?
STANDARD PROCESSING
on a small scale (using < than the equivalent of 600 kg dried cannabis/year)?
MICRO-PROCESSING
manufacture cannabis products
sell cannabis for medical purposes
SALE FOR MEDICAL PURPOSES
sell cannabis to registered clients
do testing of cannabis
ANALYTICAL TESTING
any testing (i.e., third party)
do research with cannabis
RESEARCH
do research and development

An industrial hemp licence and cannabis drug licence are two other types of licences, but are outside the scope of this guide.

Applicants may apply for any combination of class or subclass of licences in relation to the same site; however, the Minister may refuse to issue a licence, depending on the combinations, in accordance with section 29 of the *Cannabis Regulations*. Refer to Table 2: General Guide for Combinations of Licence Classes and Subclasses at a Single Site.

Table 2: General Guide for Combinations of Licence Classes and Subclasses at a Single Site

	Standard Cultivation	Micro-cultivation	Nursery	Standard Processing	Micro-processing	Sale[2]	Analytical Testing	Research
Standard Cultivation				✓		✓	✓	✓
Micro-cultivation					✓	✓	✓	✓
Nursery						✓	✓	✓
Standard Processing	✓					✓	✓	✓
Micro-processing		✓				✓	✓	✓
Sale[2]	✓	✓	✓	✓	✓		✓	✓
Analytical Testing	✓	✓	✓	✓	✓	✓		✓
Research	✓	✓	✓	✓	✓	✓	✓	

Although an applicant may wish to apply for multiple licence classes or subclasses at the same site, the CTLS may not currently allow this, depending on the combination of licences sought. In this case, a separate application may be submitted in the CTLS, or the applicant may contact Health Canada for more information.

Licence holders can conduct research and development activities within their authorized licenced activities. If the licence holder wishes to conduct research and development activities outside of their authorized licence activities, they must apply for a separate research licence.

5.3 Create an account in the CTLS

Health Canada has established the CTLS as the primary manner in which licensing applications should be submitted. The first step to create an application is to set up an individual user account in the CTLS (i.e., for the applicant who is the individual or the person who will be setting up the application for an organization). The CTLS Getting Started Guide (available on the Health Canada website) should be referred to for more information on the steps to create an account. To request an account, basic information is required including full name and salutation, email, phone number, date of birth, language preference and security information. Health Canada then

[2] Sale for medical purposes

provides an access code that can be used to enter the CTLS. Once an account is established, the user will have an Account ID in the CTLS.

Should the CTLS (or internet) not be available, the applicant may contact Health Canada directly by phone at 1-866-337-7705 or by email at cannabis@canada.ca for more guidance.

5.4 Associated individuals create accounts in the CTLS

User accounts are required for a number of individuals associated with an application. These individuals must create their own individual accounts in the CTLS before an application can be submitted to Health Canada. Individuals can use the same account information for each licence application that they may be associated with. Refer to Table 3: Individuals to be identified.

The CTLS requires that individuals who require a security clearance submit their security clearance application form before a licence application can be submitted in the CTLS. As such, the applicant may wish to have these individuals obtain their criminal record checks and apply for their security clearance, if applicable, as soon as is feasible. A licence will not be granted unless required security clearances have been granted. For information on application requirements related to personnel security clearances, refer to Appendix C: Personnel Security Clearance Application Requirements.

The applicant must ensure that the persons identified have the knowledge, qualifications, experience and ability to fulfill their responsibilities, as applicable. For more information on these elements, refer to Appendix A: Key Individuals.

The applicant should create a list of all Account IDs of individuals associated with an application. Account IDs are used to link individuals to an application in the CTLS.

An individual may hold one or multiple roles within the company, for one or more classes of licences at one site, or in some cases, multiple sites, assuming they meet all the requirements.

The CTLS requires at least one director or officer be named per corporate profile. In the case where there is no director or officer for the organization, the responsible person should be identified as an officer in this section of the CTLS.

Table 3: Individuals to be Identified

Role	Account IDs required	Security Clearance Application Required prior to Submitting Application
Directors	For all licence classes if the applicant is a corporation or a cooperative	Yes (for all except research and analytical testing)
Officers	For all licence classes if the applicant is a corporation or a cooperative	Yes (for all except research and analytical testing)
Partners	For all licence classes if the applicant is a partnership	Yes (for all except research and analytical testing)
Licence holder (where holder is an individual)	For all licence classes	Yes (for all except research and analytical testing)[3]
Responsible person	For all licence classes. Note: this can be the individual who is the licence holder	Yes (for all except research and analytical testing)[3]
Head of security	For cultivation, processing or sale for medical purposes licence only	Yes
Master grower	For cultivation licence only	Yes
Quality assurance person (QAP)	For processing licence only	Yes
Head of laboratory	For analytical testing only	No
Any individual, partnership (partners), corporation (directors and officers), or cooperative (directors and officers) in a position to directly control the applicant (for additional information refer to Appendix J: Direct Control)	For all licence classes, except research and analytical testing	Yes (for all except research and analytical testing)

[3] For analytical testing and research licence applications, a copy of government-issued ID is required in order to verify the identity of the applicant. Refer to section 6.10 of this guide for more information.

5.5 Create a corporate profile for organizations (partnership, cooperative or corporation)

The CTLS does not have a distinct section for organizations such as partnerships or cooperatives. In these cases, the "Corporate Profile" section must be used in the CTLS to provide the information required in this guide about the organization. In the "Other Registered Names" section of the CTLS corporate profile section, the applicant must clearly indicate whether they are a corporation, partnership, or cooperative.

Applicants that are partnerships, cooperatives, and corporations (in essence any applicant that is not an individual/sole proprietor) also need to create a corporate profile. Once a corporate profile is created, the individual who creates the corporate profile will have access to an Account ID for the corporation. When creating a corporate profile, the applicant lists and links (using their respective Account IDs) all the directors and officers of the corporation or cooperative, and the partners if a partnership. Once a corporate profile is created in the CTLS, the applicant can use that profile to create an application.

Creating a corporate profile has some additional requirements, as outlined below. Some requirements are needed to create a corporate profile in the CTLS, while others are required before an application is submitted.

Table 4: Corporate Profile Requirements

Requirement	***Required details to include***
The full legal name(s) of the organization	Any other name(s) registered federally or provincially under which the entity intends to do business, if applicable.
The incorporation number	As provided on the certificate of incorporation. In the case of a partnership or cooperative, if there is not an identification number, indicate "Not applicable."
Business address and contact details	The business address and the contact details used for correspondence with the corporation, not the individual applicant (e.g., head office).
Controlling organizations (noted as "Parent Corporation" in the CTLS), if applicable	The Account ID of each controlling organization. Note that any controlling organization will be required to create a corporate profile as per these requirements. Refer to Appendix J: Direct Control for more information.
Certificate of incorporation (or partnership agreement)	As part of an application, certificate of incorporation documents are required. In the case of a partnership or cooperative, a partnership/cooperative agreement is required.

Organizational chart	As part of submitting an application, a corporate organizational chart is required. The organizational chart: • Must demonstrate the relationships between senior positions within the organization and the various controlling individuals or entities, if applicable. • Must include all names and titles of senior management positions such as directors and officers of the organization and any controlling individual or entity, if applicable. Does not need to include the site-specific organizational information (e.g., the site head of security, master grower, QAP). This specific organizational information is required as part of a specific application and is to be included in the OSP.

Organization personnel	As part of an application, specific organization personnel must be identified. These individuals must have individual CTLS accounts created so that their Account IDs can be associated with the corporate profile. Directors or officers of corporations or cooperatives, and partners in a partnership must be included as part of the corporate profile.

The CTLS does not have a specific section for partners in the case of a partnership. These should be included in the officers section.

As noted earlier, where there is no director or officer for the organization, the responsible person should be identified as an officer in this section of the CTLS.

Health Canada considers any officers of a corporation named on incorporation documentation (e.g., certificate of incorporation), such as the chief executive officer, the chief operations officer and the chief financial officer (or officers equivalent in responsibility), as officers who require a security clearance. It is the responsibility of the applicant to identify all officers and directors of an organization accurately.

Prior to submitting an application in the CTLS, these individuals will also be required to submit an application to obtain a security clearance in the CTLS.

In addition, all officers, directors, partners and individuals who control the applicant must be identified and will require security clearances.

Consult the *Cannabis Regulations* for details regarding security clearance requirements.

Before an application is submitted, the corporate profile can be changed. Once an application is submitted, changes are not permitted in the CTLS. Refer to section 7.3.3 Changes to an Application/Unsolicited Information for more information.

6.0 Application Requirements: Creating an Application

This section of the guide includes the application requirements that are required for each class of licence. The requirements in this section are categorized by Requirement Areas which are found in the CTLS.

All applications are strictly and thoroughly reviewed by Health Canada against the application requirements outlined in this guide and the requirements outlined in the Regulations. Licences are only issued once all applicable requirements are met.

When creating a new licence application in the CTLS, the applicant must first identify the licence class they are applying for in the CTLS. The licence classes within the scope of this guide include:

- Cannabis licence class (cultivation, processing, sale for medical purposes)
- Research
- Analytical testing

Refer to Appendix B: Cannabis Licence Classes and Subclasses for more information.

As noted earlier, applicants may apply for more than one class or subclass of licence at the same site depending on the licence class or subclass. For example, applicants may apply for a cultivation, processing and sale for medical purposes licence in one application. However, the design of the CTLS requires a separate application be submitted for analytical testing and research licences.

This guide establishes the application requirements to obtain a licence. It is up to the applicant to confirm that all application requirements set out in this guide are submitted with the application. This guide also provides details on how to submit this information into the CTLS. Table 5 outlines the relevant sections of this guide where required information must be submitted in the CTLS, according to licence class.

When the applicant uploads a document into the CTLS, the file name should clearly identify the name of the application requirement outlined in this guide. For example, Site Survey, OSP.

Table 5: Application Guide Sections with Required Information in the CTLS, by Licence Class

Guide Section	Requirement Area	Cannabis Licence Class					
		Cultivation (Micro, Standard, Nursery)	Processing (Micro, Standard)	Sale for medical purposes (with possession of cannabis)	Sale for medical purposes (without possession of cannabis)	Analytical Testing	Research
6.1	Proposed licence holder (Licence Ownership)	✓	✓	✓	✓	✓	✓
6.2	Mailing address	✓	✓	✓	✓	✓	✓
6.3	Licence class and subclass (identified as "Site Activities" in the CTLS)	✓	✓	✓	✓	N/A	N/A
6.4	Site details (including activities)	✓	✓	✓	✓	✓	✓
6.5	Site personnel	✓	✓	✓	✓	✓	✓
6.6	Site ownership	✓	✓	✓	N/A	N/A	N/A
6.7	Notice to local authorities	✓	✓	✓	N/A	N/A	N/A
6.8	Physical security (including organizational security plan)	✓	✓	✓	✓	✓ Organizational security plan not required	✓ Organizational security plan not required
6.9	Good production practices (GPP)	✓	✓	✓	N/A	N/A	N/A
6.10	Record keeping (and reporting)	✓	✓	✓	✓	✓	✓

For a sale for medical purposes licence where there will be possession of cannabis, after selecting the licence class and subclass, the applicant should select "Site Details" and in the "room activity" area of CTLS, add "sale with possession of cannabis." This opens the additional requirement sections in the CTLS.

6.1 Proposed licence holder (licence ownership)

An application can be created for an individual or an organization. If the applicant is an organization, they must ensure that they have completed a corporate profile for the organization in the CTLS as outlined in section 5.5.

A responsible person must be designated for all applications. The responsible person has the authority to bind the licence holder, has overall responsibility for the activities conducted and is responsible for submitting the application. The responsible person is the official point of contact with Health Canada. Refer to Appendix A: Key Individuals for more information.

As per the *Cannabis Regulations*, the applicant may designate one individual as an alternate responsible person who is qualified to replace the responsible person. However, only one responsible person may be designated in the CTLS. To change the responsible person after an application has been submitted, email HC.licensing-cannabis-licences.SC@canada.ca, with the subject line "Request to change responsible person" and the application number and details. Health Canada will contact the applicant for additional details.

6.2 Mailing address

The mailing address entered must be the Canadian address where the applicant would like to receive official mailed correspondence (e.g., the licence when issued).

This is not necessarily the same as the site address or corporate address.

6.3 Licence class and subclass (identified as "Site Activities" in the CTLS)

The applicant must select the licence classes and subclasses for which they are applying.

For analytical testing and research licences, this section does not need to be filled out in the CTLS as this information is already identified when initially creating a new application.

Although there is an option in the CTLS to select "Sale – Non-Medical Online," this should not be selected.

As noted in Section 5.2, licence holders can conduct research and development activities within their authorized licenced activities. If the licence holder wishes to conduct research and development activities outside of their authorized licence activities, they must apply for a separate research licence.

6.4 Site details (including activities)

There is certain information required for a site. Requirements differ depending on the licence class (e.g., analytical testing and research requirements differ). Tables 6, 7 and 8 show the different classes of licence, namely cultivation, processing, sale for medical purposes, analytical testing and research licences.

Licensed activities cannot be conducted in a dwelling-house (i.e., a place of residence).

Licences are site specific with the exception of research, which can have multiple sites set out in a licence. If an applicant, other than an applicant for a research licence, intends to conduct licensed activities at more than one site, a separate application must be submitted for each site.

Table 6: Site Detail Requirements for Cannabis Licence Class (Cultivation, Processing, Sale for Medical Purposes)

Requirement	*Required details to include*
Complete site address	Include Canadian address as well as latitude and longitude. The CTLS allows for entry of a single address in relation to a site. Should the site have multiple addresses (e.g., several buildings in an area used exclusively by the licence holder), all site details as outlined in this section must be uploaded into the CTLS as a separate document titled Additional Site Details. This must be uploaded in the "Site Survey" section of the CTLS.
Site survey	A building location survey, location certificate or similar document, prepared and certified by a person qualified to do so in the jurisdiction where the site is located, such as a qualified land surveyor. The survey must be up to date at the point of submission.

	Include a description of the legal zoning of the proposed site and all adjacent lots.
Aerial view	A clear and legible aerial view of the proposed site and surrounding lots to within 500 metres. The aerial view must be up to date at the point of submission.
Areas (buildings and rooms, outdoor areas) and activities	Each outdoor area (if applicable), building and room must be named and this name must be provided. The names used to identify each area must match all other information submitted (e.g., on the site plan). All activities conducted in each room must also be identified (e.g., propagation, drying, labelling, etc.). More than one activity can occur in each area. Additional information may be requested to assess how the proposed activities meet all regulatory requirements.

These site details are also considered part of the site plan and must match all information provided to meet the requirements detailed in section 6.8 of this guide related to physical security.

As noted earlier, for a sale for medical purposes licence where there will be possession of cannabis
The applicant should first select "Site Details" and in the "room activity" area of CTLS, add "sale with possession of cannabis." This will open the additional requirement sections in the CTLS. All rooms where cannabis is present must be included and room details must be provided.

Each site must have at least one indoor area (building or part of a building). Cultivators may also have outdoor areas to cultivate, propagate or harvest cannabis.

Table 7: Site Detail Requirements for Analytical Testing Licence Class

Requirement	*Required details to include*
Complete site address	Include Canadian address.
Analytical testing processes to be conducted	Identify the purposes of all analytical testing activities that the applicant is proposing to conduct. For example, testing for: • Chemical (i.e., contaminants such as heavy metals, foreign matter) • Microbial* (i.e., contaminants such as yeast, molds, bacteria, aflatoxins) **Sterility appears as an independent item in the CTLS; however, it is typically captured in the context of microbial testing.* • Cannabinoid content (e.g., delta-9-tetrahydrocannabinol [THC], tetrahydrocannabinolic acid [THCA], cannabidiol [CBD], and cannabidiolic acid [CBDA]) • Dissolution/Disintegration • Pesticides • Solvent residue • Sterility • Stability (e.g., if the licence holder proposes to include a product expiry date, disintegration test for capsules) • Other (e.g., seed viability testing)

Table 8: Site Detail Requirements for Research Licence Class

Requirement	*Required details to include*
Complete site address	Primary Canadian site at which the research is proposed to occur.
Research grant	The grant number may be provided as additional information, if applicable.
Cultivation	If cannabis is proposed to be cultivated, propagated or harvested, provide information on where it is proposed to be cultivated, propagated or harvested (latitude/longitude, indoor/outdoor).
Synthesis of cannabis	Indicate whether cannabis will be synthesized.
Additional sites	If there are additional sites where activities with cannabis are proposed to occur (e.g., clinical trial conducted at multiple sites), provide the address of each site as well as the name and contact information of an individual at each site. The address of each additional authorized site will appear on the licence, if it is issued.

Intent to sell	Indicate if there is intent to sell the product of the research (e.g., cannabis plants and/or cannabis plant seeds to a licenced cultivator, researcher, cannabis drug licence or exemption holder).
Type of research	Indicate the type(s) of research (e.g., in vitro, in vivo (animal), clinical trial, plant genetics, cannabis product development, non-cannabis product development, other) that is proposed to be conducted with cannabis. An example of non-cannabis product development would be research on lights used to grow cannabis plants. Synthetic cannabinoid development should be included as "Other" and details should be included in the Research Protocol section (see below).
Research protocol	A document outlining the research that is proposed to be conducted, and the quantity of cannabis that is proposed to be possessed or produced by the applicant (e.g., kilogram, litre or number of plants or seeds as appropriate) must be provided. This must also include the duration for which the research licence is sought (up to five years).
For an in vivo (animal) study: FDA authorization, if applicable	For an in vivo study where FDA authorization is required, the Experimental Study Certificate must be submitted as part of the licence application. Additional information on the Experimental Study Certificate can be found in the Experimental Studies Certificate Application Form for a Veterinary Drug.
For a clinical trial: No objection letter for a clinical trial	For a clinical trial, the applicant must first obtain a no objection letter from Health Canada, which must be submitted as part of the licence application. Additional information on clinical trial application requirements can be found in the Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications as well as on the Health Canada website.

A research licence is granted for a specific research project. A research licence may be effective for the duration of the research project up to a maximum of five years. If the research project needs to continue past the expiry date of the licence, the licence holder may apply for a renewal of the licence. More than one type of research may be conducted under a single licence. The research protocol must describe all types of research to be conducted.

Depending on the type of activities proposed to be conducted with cannabis and the quantity of cannabis on-site, additional security measures may be required, such as security clearances of key personnel. The licence may also be subject to additional conditions, such as the need for an OSP or increased physical security measures. Each submission will be assessed on a case-by-case basis.

6.5 Site personnel

As outlined in section 5.4 of this guide, as part of the application the applicant should identify individuals that must have accounts and security clearances. The individuals will differ based on the licence class or subclass as well as the type of licence holder (i.e., if it is an individual or a corporation, cooperative or partnership). These individuals should create CTLS accounts and provide their Account IDs to the applicant. Some of these individuals need to be identified if the applicant is creating a corporate profile. Other individuals need to be identified within the "Site Personnel" section of the CTLS. The applicant must ensure that the persons identified have the knowledge, qualifications, experience and ability to fulfill their responsibilities, as applicable. For more information, refer to Appendix A: Key Individuals.

Qualifications are only required to be submitted for the QAP for a processing licence, and the head of laboratory for an analytical testing licence.

An individual may hold one or multiple roles for a licence, for one or more classes of licences at one site, or in some cases, multiple sites, assuming they meet all the requirements.

For cultivation, processing and sale for medical purposes licences
The CTLS requires that a security clearance application form be submitted for at least one individual in each position that requires a security clearance.

In the case where an applicant wishes to designate an alternate, as authorized under the Regulations, this may be done at any time. However, any alternate must also hold a valid security clearance, as applicable, before assuming the duties of the position. The Minister may also specify other individuals that must hold a security clearance, either by name or position. Should this occur, the licence holder or applicant is notified in writing.

Table 9: Site Personnel Requirements

Requirement	*Required details to include*
Identification of personnel	Specific individuals must be identified that are associated with an application in the CTLS, as follows: **Cultivator (standard, micro or nursery):** Head of security, alternate head of security if applicable; master grower, alternate master grower if applicable **Processor (standard or micro):** Head of security, alternate head of security if applicable; QAP, alternate QAP if applicable **Sale for medical purposes:** Head of security, alternate head of security if applicable **Analytical testing:** Head of laboratory, alternate head of laboratory if applicable **Research:** None. *The responsible person must be identified within the "Licence Ownership" section of the CTLS as noted in section 6.1 of this guide.* To associate these individuals with an application, their Account IDs need to be included in the CTLS. **For research licences:** The CTLS asks for an authorized person; however, this is not required for research licence applications. Only the responsible person should be provided. In addition, the CTLS asks for qualifications for the responsible person, although these are not required for a research licence application. A blank document needs to be uploaded into the CTLS indicating that these are not required.
Qualifications for the QAP *(Processing licence only)*	Submit details of the proposed individual's qualifications, and any designated alternate QAP, demonstrating they have the training, experience and technical knowledge related to all the requirements in Part 5 (GPP requirements) of the *Cannabis Regulations* including: • Development and approval of SOPs • Pest control management and pesticide testing • Quality control relating to storage and shipment of substances • GPP as they pertain to facilities (including air filtration), equipment and sanitation • Complaint management • Approving product quality prior to release for sale • Analytical testing and validation of testing methods • Residues of solvents (for cannabis oil), if applicable

Table 9: Site Personnel Requirements

Requirement	*Required details to include*
	• Microbial and chemical contaminants • Disintegration/dissolution of cannabis capsules, if applicable • Cannabinoid content (THC, THCA, CBD and CBDA, as applicable) • Sample collection and retention In addition, the QAP typically handles recalls and adverse reaction reports. The applicant should submit the individual(s)' resume and any other information that would be relevant such as a letter of reference or a copy of their diploma, degree, or certificate or transcripts that may be applicable. A proposed work schedule and a summary of the roles and responsibilities of the QAP and their alternate if applicable should also be provided to demonstrate how the QAP will be able to complete all the required activities to maintain compliance.
Qualifications for the head of laboratory *(Analytical testing licence only)*	Submit details of the individual's qualifications, and any designated alternate head of laboratory, as they relate specifically to the duties of the position. • The applicant should submit proof of the individual(s)' education, such as a copy of their degree, their resume, and any other information that would be relevant such as a letter of reference, or a copy of their university transcripts.

6.6 Site ownership

This section does not apply to analytical testing, research or sale for medical purposes without possession licences.

The following information is required to confirm site ownership:

Table 10: Site Ownership Requirements

Requirement	***Required details to include***
Site owner	If the site is owned by the individual or the corporation applying for the licence, this must be indicated by linking the Account ID in the CTLS. If the site is owned by another individual(s) or corporation, a site owner consent form is required (see section below).
Site owner consent form, if the site or any portion of the site is not owned by the applicant	A declaration, signed and dated by the site's owner— or, if the owner is a corporation, by an authorized representative of the owner — consenting to activities with cannabis being conducted at the site. The consent form must contain: • the full address of the site or any portion of the site for which the owner is not the applicant • the class and subclass if applicable of the licence being applied for, and the proposed activities to be conducted on-site • a declaration signed by all owners of the site stating that they: a) are the owner(s) of the site, as described b) are fully aware of the activities with cannabis that the applicant proposes to conduct at the site c) consent to those activities with cannabis being carried out at that site

6.7 Notices to local authorities

Notice to local authorities is not required for analytical testing, research and sale for medical purposes without possession licences.

Prior to submitting an application in the CTLS, applicants for licences to cultivate, process and sell for medical purposes (with possession of cannabis) must provide with their application a copy of the written notice to local authorities who are located in the area of the proposed site, as part of their application.

More specifically, the notice must be provided to a senior official of the following local authorities:

- the local government
- the local fire authority
- the local police force or Royal Canadian Mounted Police detachment (RCMP) that is responsible for providing policing services to that area

The content of the notice must include:

- the name of the applicant
- the expected date on which the applicant will submit the application to Health Canada
- the class and subclass if applicable of licence that is being sought and the cannabis-related activities that are expected to be conducted under that licence
- the site address, and address of each building on site if applicable, at which the applicant is expecting to conduct cannabis-related activities

In order to submit an application, the following information is required:

Table 11: Notice to Local Authorities Requirements

Requirement	***Required details to include***
Notice to local authorities	The date of each notice, and the name, title and address of the senior official to whom it was addressed. A copy of the actual notices provided to: • the local government • the local fire authority • the local police force or Royal Canadian Mounted Police detachment that is responsible for providing policing services to that area

6.8 Physical security including organizational security plan

Requirements for physical security apply to all licence classes, but differ depending on the licence class, and subclass if applicable. For instance, an OSP is not required for analytical testing and research licences. For more information, refer to the *Cannabis Regulations* and Appendix D: Physical Security Requirements.

For sale for medical purposes without possession of cannabis licences:
Although physical security requirements do not apply to licences for sale for medical purposes without possession, other requirements included in this section, such as the OSP, do.

The applicant should upload the required information in the "Record Keeping" section of the CTLS as the physical security section of the CTLS will not be visible for a sale for medical purposes without possession licence.

Table 12: Physical Security Requirements

Requirement	*Required details to include*
Site plan **(Not required for sale for medical purposes without possession licence)**	The site plan must include the following details. • The perimeter of the site must be clearly identified. • Indicate if the building is a multi-unit building or a stand-alone site (i.e., single unit). If it is a multi-unit building, the site perimeter should be placed accordingly and all units must be labelled with information on their current use (i.e., company name). • The location of any outdoor cultivation area must be clearly identified. For any outdoor area, the latitude and longitude coordinates for all four corners must be indicated. • All applicable security features must be illustrated and identified. • The floor plan(s) of the building(s), including rooms where operations, grow and storage activities, as applicable, take place must be clearly delineated. • All applicable security features must be illustrated and identified, • Product flow between the rooms must be indicated. If there are areas, including buildings, that will not be used exclusively by the applicant, or areas that will be used by the applicant to conduct activities other than activities with cannabis, these areas must be outside of the proposed site perimeter. The plan should also include a detailed description of how each of the applicable physical security requirements will be met, as found in the *Cannabis Regulations* and Appendix D: Physical Security Requirements. The table in Appendix D may be used as a template to provide a detailed description of each of the physical security measures. The nomenclature in the plans must be consistent with what is submitted in the "Site Details" section of the CTLS (i.e., for outdoor areas and indoor areas and rooms). **For a micro-cultivation and nursery licence,** the site plan should delineate the surface areas to demonstrate how the site meets the surface area threshold. As well, it should indicate whether the surface area comprises multiple surfaces (e.g., is vertically arranged). **For micro-cultivation, plant surface area cannot exceed 200 m^2 (includes multiple surfaces such as surfaces vertically arranged). For nursery seed production the total surface area cannot exceed 50 m^2 (for all the parts of budding or flowering plants).**

Organizational security plan **(Not required for analytical testing and research licences)**	An OSP must be submitted that includes the information detailed below.
	1) Head of security: In addition to the information already provided about the head of security (name, contact information), a proposed work schedule including hours of work, a summary of the roles and responsibilities, as well as emergency contact information must be provided. The same information for any identified alternate head of security must also be provided.
	2) Site organizational chart: A chart outlining the structure of the organization showing the relationships of the officers and management positions within it, including supervisors, must be provided. The chart should include the titles but not the names of all individuals who require a security clearance as well as any other positions that have significant influence on strategic business decisions, day-to-day operations and the movement of significant amounts of money or cannabis. For example, this chart must identify all persons who have management responsibility for the following activities or have the following knowledge: • any product movement beyond minimal amounts • setting operational procedures, including SOPs • responsibility for inputting data into CTLS for cannabis tracking purposes • sensitive security or business knowledge • financial controls, including but not limited to the ability to enter into contracts for goods and services. A short description of the roles of each position indicated in the organizational chart must also be submitted.

3) List of individuals in key positions and security status: A list of all proposed individuals in key positions (those identified in the corporate profile and key individuals as described in section 5.4 and Appendix A: Key Individuals), as well as any proposed alternate individuals indicated as such, including their names, date of birth, positions, Account IDs and security clearance status.

For an organization: A list of all officers, directors, partners and any individual who exercises, or is in a position to exercise, direct control over the corporation, cooperative or partnership as identified in the organizational chart, including their names, date of birth, positions, Account IDs and security clearance status.

Other individuals: Indicate whether there are other proposed individuals or positions that the applicant believes should hold a valid security clearance due to the nature of their work and possible security risks to the organization. For example, the applicant may want to propose security clearances for positions/individuals that have unsupervised or uncontrolled access to sensitive records and information, information technology infrastructure, or access card records (e.g., those identified in the site organizational chart). Note that it is not a requirement to identify additional positions/individuals, but this could be considered by the applicant as a means to mitigate identified security risks. Information including other individuals' name, position title and nature of the position should be provided.

4) Physical security: Include an attestation by the head of security that they have reviewed the physical security of the site including the site plan and how the physical security requirements are to be met.

5) Cannabis tracking and record keeping: A list of all names, titles and contact information for all individuals in the organization who will input data into the CTLS for cannabis tracking purposes must be provided. In addition, a description of the record keeping method to be used to ensure that all cannabis is tracked from the time it enters the facility to when it leaves the facility must be provided. Reference can be made to information provided to meet the record keeping and reporting requirements.

6) Security awareness and training: A description of the steps that the proposed head of security intends to take to ensure that guests and all employees/contractors of the site are trained and aware of security requirements and procedures, including:

- initial training and awareness for all new employees/contractors or targeted employee groups
- ongoing training and awareness for all employees/contractors or targeted employee groups
- security briefings for guests

7) SOPs: A list of SOPs and a short description of each demonstrating the procedures in place to prevent, detect and respond to potential security incidents as outlined in Appendix E: Organizational Security Plan SOP Priority Areas must be provided.

8) Other security elements: A description of other security elements or features of the facility that would be helpful in evaluating the application (e.g., if the applicant will have measures in place to protect information technology infrastructure from a cyber-attack, business continuity plans, etc.)

9) Approval: An attestation signed and dated by the proposed head of security and proposed responsible person that the organizational security plan has been approved must be provided.

6.9 Good Production Practices

Good production practices (GPP) requirements apply to a number of activities across many licence classes.

Only some of these must be demonstrated at the time of application. However, GPP compliance may be verified at any time by Health Canada. Applicants for analytical testing, research, and sale for medical purposes without possession licences do not need to demonstrate compliance with GPP as part of the licensing application process.

As part of the licensing application process, the applicant is required to provide a Good Production Practices Report that clearly demonstrates how the GPP requirements will be met. The *Cannabis Regulations* and Appendix F: GPP Requirements provide more information on what is required.

Table 13 shows the elements that are required to demonstrate how the GPP requirements will be met.

Table 13: GPP Requirements

Requirement	***Elements to demonstrate that GPP requirements will be met:***
Good Production Practices Report	The Good Production Practices Report should include a detailed description of how each of the applicable GPP requirements outlined in the *Cannabis Regulations* and Appendix F: GPP Requirements will be met. The table in Appendix F may be used as a template to include a detailed description of each of the GPP measures.
Starting material authorized quantities **(Cultivation licence only)**	In the case where the applicant intends to use cannabis plants or cannabis plant seeds that were not obtained in accordance with the former *Access to Cannabis for Medical Purposes Regulations* or with the *Cannabis Regulations* or from a person authorized to sell cannabis under a provincial Act, they must provide a declaration, signed and dated by the applicant, indicating the quantity of cannabis plants and cannabis plant seeds that they will have in their possession on the effective date of the licence. This declaration can be provided to Health Canada at any time prior to licensing, including when the applicant is contacted by an officer as part of the review process.

6.10 Record Keeping (and Reporting)

Required for all licence types, based on the regulatory requirements.

There are a number of regulatory requirements for record keeping and reporting that must be met by a licence holder. The applicant is encouraged to refer to the *Cannabis Regulations* and Appendix G: Record Keeping Requirements for details about record keeping required for the licensing process, and to consult the *Cannabis Regulations* to obtain an understanding of the post-licensing regulatory record keeping and reporting requirements.

Table 14: Record Keeping (and Reporting) Requirements

Requirement	***Required details to include***
Record keeping method	Include a description of record keeping methods to be used to ensure that all record keeping and reporting requirements are met as outlined in the *Cannabis Regulations* and in Appendix G: Record Keeping Requirements. Details must include: • the name of the system that the applicant intends to use and a copy of the manual/pamphlet if applicable • details explaining how that system will capture, report and reconcile the information required
Record keeping examples	Examples (e.g., templates) pulled from the record keeping system to demonstrate how each requirement will be captured.
Copy of government issued identification **(Analytical testing and research licences only)**	In order to verify the identity of the applicant and/or responsible person, a copy of government-issued identification must be provided. NOTE: There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the "Record Keeping Description" section.
Key investor reports **(Cultivation, processing or sale for medical purposes**	An applicant seeking a licence for cultivation, processing or sale for medical purposes that does not trade its shares on the public market must provide information on key investors as part of an application. Refer to Appendix I: Key Investors for more information. The information includes the key investor's name and address; a description of the means by which the key investor exercises, or is in a position to exercise, control over the licence

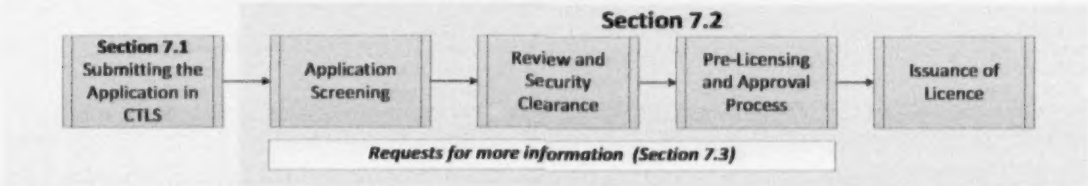
Table 14: Record Keeping (and Reporting) Requirements

Requirement	*Required details to include*
licences only)	holder; details regarding any benefit received as a result of being an investor; and whether the controlling interest has been, will be, or could be assigned, pledged, mortgaged, hypothecated or sold, in whole or in part, to any person. If there are no investors, an attestation must be provided in this regard. Refer to section 241 of the *Cannabis Regulations* for the additional record keeping and reporting requirements relating to investors once licenced. NOTE: There is no specific section in the CTLS to upload this information. This information should be uploaded as an attachment under the Record Keeping Description section.
Detailed description of the record keeping methods proposed for additional requirements for sale for medical purposes **(Sale for medical purposes licence only)**	Include a description of the record keeping methods that will capture the following information: • medical client registration information • filling of orders and refusal to fill orders • medical documents provided by clients • communication with provincial or territorial professional licensing authorities This information should be uploaded as an attachment under the Record Keeping Description section.

7.0 Submitting an Application and Administrative Procedures

Once the applicant has included all of the requirements in the application within the CTLS and is ready to submit the application, the additional steps in the licensing process will begin as outlined in Figure 3: Steps following submission of an application.

Figure 3: Steps following submission of an application


Section 7.2
Section 7.1 Submitting the Application in CTLS
Application Screening
Review and Security Clearance
Pre-Licensing and Approval Process
Issuance of Licence
Requests for more information (Section 7.3)

7.1 Submitting the application

Once the applicant has input all required information, they can submit their application. This involves the following steps:

- Self-Identification: The CTLS includes an opportunity to self-identify as Indigenous affiliated.[4] A no response includes not wanting to self-identify.
- Submission (declarations and attestations): Prior to submitting the application, the applicant, through their proposed responsible person, must electronically attest to the following:
  - that the proposed personnel submitted as part of the application are familiar with the provisions of the *Cannabis Act* and its Regulations that will apply to the licence
  - that none of the activities that the applicant is proposing to conduct in the application will be conducted, or records of these activities maintained, at a dwelling-house
  - that all information and documents submitted in support of the application, are, to the best of the applicant's knowledge, correct and complete
  - that the person submitting the application has the authority to bind the application/applicant and to have overall responsibility for the management of the activities to be conducted under the licence

[4]Indigenous affiliation can include any person or persons of First Nation, Inuit and/or Métis descent or any community, corporation or business associated with a First Nation, Inuit and Métis government, organization or community.

Once the application is submitted, it appears in the "Submitted Licence Applications" section of the CTLS. Each application will have a unique Licence Application ID. All correspondence with Health Canada in relation to the application should include this identifier in the subject title.

An applicant may check the status of their application in the CTLS at any time during the application process. For more information, refer to Appendix H: Application Status Meanings in CTLS.

7.2 After submission

Once an application is submitted in the CTLS, there are a series of steps Health Canada undertakes to review and issue the licence as outlined below. It is important to note that in accordance with 62(5) of the *Cannabis Act*, the Minister may request the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to consider the application. This would be in the form of a request for more information as outlined in section 7.3.1 of this guide.

- 7.2.1 **Application screening:** During screening, the application and attached documents are assessed for completeness, legibility and ability to be further assessed. There is a 30 day service standard for completion of screening of the application by Health Canada.

- 7.2.2 **Review and security clearance:** Once an application has passed the screening stage, and security clearance applications are being processed, the application will undergo a detailed review to verify that the requirements are met. Health Canada will work with the RCMP on security clearance applications.

- 7.2.3 **Pre-licensing and approval process:** Once Health Canada completes the detailed review of the submitted application, Health Canada provides the applicant with a confirmation of readiness email. This email will prompt the applicant for information to demonstrate that there is a functioning facility/building at the site address. The applicant will be required to provide a site evidence package with documentation including, but not limited to, detailed video walkthroughs of both the interior and exterior of the site, and site and building plans including descriptions and photographs that clearly detail facility completion.

  Following the review of this information, an on-site pre-licence inspection by Health Canada inspectors may be deemed necessary prior to further licensing decisions. If an inspection is required, the inspection team will contact the applicant to schedule the pre-licence inspection. In the case where an on-site pre-licence inspection is not required, the licence issuance will be based on the thoroughness of information found in the site evidence package.

As the regulatory requirements for each licence type vary, so do the requirements for the site evidence package. When an applicant reaches this stage in the application process, they will be informed of what specific information is required.

- 7.2.4 Issuance of licence: Once all information has been reviewed, including the results and observations from a pre-licence inspection, if necessary, and all security clearances have been granted, an initial licence for authorized activities is issued. A hard copy of the licence as well as an accompanying issuance letter detailing any conditions around the issued licence is mailed to the identified mailing address. In addition, all security-cleared key personnel are sent letters regarding the status of their security clearances for that site, under that application. Following issuance of the licence, Health Canada holds a teleconference with the new licence holder to discuss the licence, including any conditions.

Licence holders must ensure that the quality of cannabis products they produce meet all applicable requirements. When a licence holder is first licenced, activities may be limited, particularly prior to being authorized to conduct the activity of sale for medical purposes. This graduated licensing is for the purpose of verifying that cannabis products intended for sale meet all of the quality standards set out under the *Cannabis Regulations*.

7.3 Administrative Procedures

7.3.1 Receiving and responding to a request for more information

It is the applicant's responsibility to meet all of the licensing requirements. If information submitted as part of the application is unclear or requires further detail to show how it meets the requirements, Health Canada asks the applicant to clarify this information through a request for more information.

In these cases, Health Canada strives to be clear about what information is needed from the applicant. If the applicant is unclear about what is required to respond to the request for more information, they may contact Health Canada by email or phone for further guidance (refer to section 8.0 of this guide). Note that it is not a requirement to retain the services of a third party (e.g., consultant) to prepare responses to Health Canada.

A request for more information will be emailed to the responsible person. The applicant must respond by email, generally within 30 calendar days of the request. Some requirements for responding to requests for more information include:

- Responses should be comprehensive and comment on each of the elements noted in the request for additional information.
- The applicant should not resubmit a revised version of the original documents unless requested to do so, but should provide a clear and detailed response specific to each point requested. This can be submitted in tabular format or in a report format with subheadings associated with each item noted in the request.
- It is important to be as specific and as detailed as possible when addressing each section. Incomplete responses may delay processing or lead to a refusal to consider an application.

If the applicant wishes another representative to be the primary recipient of communications or receive a copy of all communications, the applicant must provide a written and signed consent to Health Canada that permits Health Canada to communicate details about the application to the third-party individual. This must be sent via email to HC_cannabis_licensing@canada.ca indicating the application number and with the subject line "Application Representative".

7.3.2 Refusals and withdrawals

Health Canada may refuse to consider an application if any of the required information is not provided.

In addition, Health Canada may refuse to issue a licence under circumstances set out in the *Cannabis Act* and its Regulations. These include:

- Issuing a licence is likely to create a risk to public health or public safety including the risk of diversion
- There are reasonable grounds to believe that false or misleading information has been submitted
- The applicant has contravened the *Cannabis Act*, the *Controlled Drugs and Substances Act*, the *FDA* or any associated regulations, including an order or a condition of another licence, in the past 10 years
- The applicant is a young person, an individual who is not ordinarily resident in Canada or an organization that was incorporated, formed or otherwise organized outside of Canada
- A security clearance associated with the application has been refused or cancelled
- An individual who is required to hold a security clearance does not hold one
- The combination of classes or subclasses of licences proposed at the same site. For further details refer to Table 2: General Guide for Combinations of Licence Classes and Subclasses at a Single Site and section 29 of the *Cannabis Regulations*.
- The Minister is of the opinion that refusal is in the public interest

In these cases, Health Canada may send an intent to refuse notice, either to refuse to consider an application, or to refuse to issue a licence. This intent to refuse notice will generally provide the applicant with 30 days to respond, after which a notice of refusal will be issued.

The notice of refusal officially closes the file and sets out the specific reasons or deficiencies that resulted in the decision to refuse to consider the application or issue a licence. All decisions to refuse an application are without prejudice to filing a new application for a licence. If an applicant wishes to submit a new application at a future time, it will be processed as such. Information and data submitted to support an application will not be returned to the applicant.

At any time during the review of their application, the applicant may withdraw the application through the CTLS. Withdrawal of an application is without prejudice to re-filing. If an applicant wishes to resubmit an application at a future time, the application will be processed as a new application. Information and data submitted to support the original application will not be returned to the applicant.

For personnel security clearances, if the intent is to refuse to grant a security clearance, the individual applicant will be notified in writing of the basis for the intent to refuse and will be provided with a minimum of 20 days to make written representations. The individual applicant as well as the associated licensing applicant will be notified in writing if the Minister refuses to grant the clearance.

If an individual's security clearance is refused or cancelled, the individual who has been refused a security clearance cannot submit a new application for a security clearance until the circumstances that resulted in the refusal or cancellation have changed or until five years have elapsed after the refusal or the cancellation.

7.3.3 Changes to an application/unsolicited information

Once an application is submitted, changes cannot be made to the application within the CTLS. If a change is required, the applicant must contact HC.licensing-cannabis-licences.SC@canada.ca. The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email.

8.0 Contact Us

For questions related to a specific licence application, an email may be sent to: HC.licensing-cannabis-licences.SC@canada.ca. The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email. Meeting or teleconference requests are evaluated on a case-by-case basis.

For other general questions about the *Cannabis Act* and its Regulations outside of a specific application, including those related to the CTLS, email: cannabis@canada.ca.

Alternatively, the Cannabis Legalization and Regulation Branch may be contacted by phone at 1-866-337-7705.

9.0 Feedback – Help Us Improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing applicants and licence holders with the information they require in order to be compliant with the *Cannabis Act* and its Regulations.

Health Canada appreciates receiving your feedback on whether this guide was useful and would welcome your suggestions for improvement. Please send us your feedback by email to: cannabis@canada.ca and indicate in the subject line: "Feedback on Application Guide".

Your feedback will help us improve this guide and better serve all applicants and licence holders.

Appendix A: Key Individuals

*Note that for the purposes of an application, other individuals may require accounts and/or security clearances in addition to the key individuals identified in this table. Refer to the *Cannabis Regulations* and Section 5 of this guide for more information.

✓ Required to be identified SEC- Security Clearance Required

Individuals	*Responsibilities and Qualifications (as defined in the Regulations)*	Cultivation			Processing		Sale for Medical Purposes	Analytical Testing	Research
		Standard	Micro	Nursery	Standard	Micro			
Licence Holder (as an Individual)	• Overall responsibility for the licence	✓SEC	✓SEC	✓ SEC	✓ SEC	✓ SEC	✓ SEC	✓	✓
Responsible Person	• A holder of a licence must retain the services of one individual as the responsible person who has the authority to bind the licence holder • Has overall responsibility for the activities conducted by the licence holder • Must have sufficient knowledge of the provisions of the Act and Regulations that apply to the holder of the licence *May designate one qualified alternate* *Will be the official point of contact with Health Canada and through the CTLS*	✓SEC	✓SEC	✓SEC	✓SEC	✓SEC	✓SEC	✓	✓
Head of Security	• Responsible for ensuring that the physical security measures comply with Part 4 of the *Cannabis Regulations* • Responsible for the OSP *May designate one qualified alternate*	✓SEC	✓SEC	✓SEC	✓SEC	✓SEC	✓SEC		
Master Grower	• Responsible for the cultivation, propagation and harvesting of cannabis • Must be familiar with the provisions of the Act and Regulations that relate to his or her activities. *May designate one qualified alternate*	✓SEC	✓SEC	✓SEC					

Individuals	*Responsibilities and Qualifications (as defined in the Regulations)*	Cultivation			Processing		Sale for Medical Purposes	Analytical Testing	Research
		Standard	Micro	Nursery	Standard	Micro			
QAP	• Responsible for assuring the quality of the cannabis before it is made available for sale • Required to have the training, experience and technical knowledge related to the requirements of the GPP requirements of the Regulations • Responsible for investigating every complaint received in respect of the quality of the cannabis and, if necessary, taking corrective and preventative measures • Responsible for approval of methods and procedures related to GPP *May designate **up to two** alternate QAPs who can replace the QAP, if and when required. These alternates must be identified in advance and requires approval from Health Canada, because there are specified qualifications for this position*				✓SEC	✓SEC			
Head of Laboratory	• Work at the licensed site and be responsible for the testing activities under section 91 of the *Cannabis Regulations* (testing of each lot/batch for composition) • Required to be familiar with the applicable provisions of the Act and associated regulations • Have knowledge and experience related to the duties of the position • Possess a degree in a science that is related to the work to be carried out awarded by either a Canadian university or, if awarded by a foreign university, one that is recognized by a Canadian university or Canadian professional association *An applicant may designate **one or more** alternates who can replace the Head of Laboratory, if and when required. These alternates must be identified in advance and requires approval from Health Canada, because there are specified qualifications for this position*							✓	

Appendix B: Cannabis Licence Classes and Subclasses

This table provides a summary of the cannabis licence classes and subclasses, and activities that can be authorized under the *Cannabis Regulations*. The *Cannabis Regulations* should be referred to for additional detail. In order to conduct any of the activities, they must be authorized by the licence.

CTLS Licence Class[5]	Licence Class[6]	Subclass	Restrictions	Authorized Activities (if authorized by licence)[7]	Notes
Cannabis	Cultivation	Standard Cultivation		• Possess cannabis • Obtain dried or fresh cannabis, cannabis plants or cannabis seeds by propagating, cultivating, harvesting • For the purpose of testing, alter the chemical or physical properties of the cannabis • Sell and distribute dried cannabis, fresh cannabis, cannabis plants or seeds to other licence holders (cultivators, processors, analytical testers, researchers, cannabis drug licence holders), with the exception that dried cannabis or fresh cannabis cannot be sold to the holder of a nursery licence • Sell and distribute cannabis plants or seeds to a licenced nursery • Sell and distribute cannabis products that are plants or seeds to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act • Send and deliver cannabis products that are plants or seeds	• An applicant may apply for a standard cultivation licence, even with a proposed plant surface area of less than 200 square metres but standard cultivation requirements will apply in this case • Cultivation may be conducted indoors or outdoors
	Cultivation	Micro-Cultivation	• Plant surface area cannot exceed 200m^2 (includes multiple surfaces such as surfaces vertically arranged)		• Cultivation may be conducted indoors or outdoors but the cannabis plant surface area includes any indoor/outdoor areas at any single time)

[5] For the purposes of CTLS, users are required to first indicate whether they will be applying for a Cannabis, Analytical Testing, or Research Licence. The user will then need to specify the cannabis licence class or subclass (as specified by the *Cannabis Regulations*) for which they intend to apply

[6] Should the user select 'Cannabis' as a licence class in CTLS, they will then need to specify the cannabis licence class or subclass (as specified by the *Cannabis Regulations*) for which they intend to apply

[7] Licence holders can conduct research and development activities within their authorized licenced activities. If the licence holder wishes to conduct research and development activities outside of their authorized licence activities, they must apply for a separate research licence

CTLS Licence Class[5]	Licence Class[6]	Subclass	Restrictions	Authorized Activities (if authorized by licence)[7]	Notes
				to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act • Conduct ancillary activities (e.g., drying, trimming, milling, etc.)	
Cannabis	Cultivation	Nursery	• For seed production, total surface area of no more than $50m^2$ must contain all the parts of budding or flowering plants • Maximum of 5kg of flowering heads harvested from plants with the exception of seeds • Must destroy the flowering heads (with the exception of the cannabis plant seeds), leaves and branches of the plants within 30 days of harvesting them	• Possess cannabis • Obtain cannabis plants or plant seeds by propagating, cultivating, harvesting • For the purpose of testing, alter the chemical or physical properties of the cannabis • Sell and distribute cannabis plants or seeds to other licence holders (cultivators, processors, analytical testers, researchers, cannabis drug licence holders) • Sell and distribute cannabis products that are plants or seeds to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act • Send and deliver cannabis products that are plants or seeds to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act • Conduct ancillary activities (e.g., drying)	• Cultivation may be conducted indoors or outdoors
	Processing	Standard Processing		• Possess cannabis • Produce cannabis, other than obtaining it by propagating, cultivating, or harvesting • For micro-processing, the cannabis cannot be obtained by	• All activities must be conducted indoors

CTLS Licence Class[5]	Licence Class[6]	Subclass	Restrictions	Authorized Activities (if authorized by licence)[7]	Notes
Cannabis	Processing	Micro-processing	• Maximum of 600kg of dried cannabis (or equivalent) in 1 calendar year Note: If licence holder also holds a micro-cultivation licence for the same site and the cannabis comes exclusively from that site, this maximum quantity does not apply.	synthesis. • Sell and distribute cannabis to other licence holders (processors, analytical testers, researchers, cannabis drug licence holders) • Sell and distribute to licenced micro-cultivators or standard cultivators: o dried cannabis, fresh cannabis, cannabis plants, or cannabis seeds o cannabis produced for the purposes of testing that is necessary to determine the chemical characterization of cannabis, such as a reference standard • Sell and distribute to licenced nursery: o cannabis plants or seeds o cannabis produced for the purposes of testing that is necessary to determine the chemical characterization of cannabis, such as a reference standard • Send and deliver cannabis products to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act • Send and deliver cannabis products that are plants or seeds to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act	

CTLS Licence Class[7]	Licence Class[8]	Subclass	Restrictions	Authorized Activities (if authorized by licence)[9]	Notes
Cannabis	Sale for Medical Purposes	N/A	• Must sell cannabis products in the packaging in which they were sold or distributed to them	• Possess cannabis products • Sell or distribute cannabis products to a client • Sell or distribute cannabis products to a licence holder (with the exception of a cultivator) • Sell or distribute cannabis products that are dried, fresh, plants or cannabis seeds to micro-cultivator or standard cultivator • Sell or distribute cannabis products that are plants or plant seeds to a licenced nursery • Sell or distribute cannabis products other than plants or seeds to a hospital employee	• Requirements for the application for a sale for medical purposes licence with possession of cannabis differ from those that do not have possession. Refer to Section 6 of this guide for more information • Sale is to registered clients authorized to use cannabis for medical purposes
Analytical Testing		N/A	• All samples of a lot or batch of cannabis must be destroyed within 90 days of the completion of the testing • If testing is not started within 120 days of sample receipt, samples must be destroyed	• Possess cannabis • Alter the chemical or physical properties of the cannabis for the purposes of testing	
Research		N/A		• For the purpose of research, possess, produce, and transport, send, or deliver cannabis between sites that are authorized by the licence • Sell cannabis plants or seeds to a cultivator, another researcher, cannabis drug licence holders, the Minister, exemption holder	• In general, research licence holders will be required to destroy all cannabis in their possession upon the completion of their research project as part of the terms and conditions of their licence. They may be authorized to conducted limited sale and distribution activities such as the sale of cannabis plants and seeds to another researcher or a cultivation licence holder.

Appendix C: Personnel Security Clearance Application Requirements

Each individual requiring a security clearance must submit a Security Clearance Application in the CTLS with the following information:

- **Biographical information:** Including name, date of birth, preferred official language, location of birth, birth certificate number and issuing province or territory, and descriptors such as eye and hair colour, weight and height. A valid piece of photo identification issued by the government (Canada or province or territory) or a copy of the passport with the passport number, country, expiry date and photograph must also be provided.
- **Criminal charges and convictions:** The applicant must obtain a criminal record check and include information about past criminal charges and convictions in the application.

As part of the criminal record check process, the applicant must provide a "Security Clearance Fingerprint Third Party Consent to Release Personal Information Form." This must be provided to the local police force, the RCMP, or a private fingerprinting agency accredited by the RCMP. The form authorizes the RCMP to release the criminal record check and fingerprint verification results to Health Canada. Following fingerprinting, a document control number (DCN) is provided on the form, which is used as the identifier for the record check. Refer to the Health Canada website for this form.

- **Residential addresses:** Must be included for the past five years, prior to the time of application.
- **Employment, education and unemployment history:** Must be included for the past five years, prior to the time of application.
- **Marital status:** Must include details of current and any previous spouses or common-law partners over the last five years.
- **Time spent outside of country of residence:** The applicant must provide the dates, destination and purpose of travel for any travel exceeding 90 days in the past five years.
- **Signed consent:** As part of this application, **a consent and certification form** must be uploaded with a signature by the individual. Refer to Appendix K: Security Clearance – Consent and Certification Form.
- **Submission:** The applicant must attest that the information, including supporting documents, in the application is true prior to submission.

Appendix D: Physical Security Requirements

Below is a summary of the physical security requirements under the *Cannabis Regulations*. The *Cannabis Regulations* should be referred to for further information. Information demonstrating how these requirements will be met must be submitted as part of the licence application as outlined in section 6.8 Physical Security (Including Organizational Security Plan) of this guide. Examples of evidence that can be submitted to demonstrate that the requirements are met are provided in the table below. This table may be used as a template to provide a detailed description of each of the measures. This information must be submitted along with the site plan and floor plans(s) including storage areas as part of the Physical Security Plan package. All elements described should be clearly marked and labelled with unique identifiers on the floor plans. It should be noted that these measures are the minimal requirements. Additional physical security measures could be required as part of the conditions of a licence.

Requirement (Reference to Cannabis Regulations)			Examples of evidence to demonstrate how the requirement would be met	Standard Cultivation, Standard Processing and Sale for Medical Purposes (cannabis on site)	Micro-cultivation, Micro-processing and Nurseries	Analytical Testing	Research
Site Design and Physical Barriers	Design	Site must be designed in manner that prevents unauthorized access (s. 63, s.74(a) and s.77)	• Design of the site and how it will prevent unauthorized access. • Design of and materials used in the construction of the physical barriers, as applicable, including walls, floor/ceiling, door, etc. to ensure prevention of intrusion. • Any access controls at entry/exit points of the site such as windows, doors, vents, etc. Details could include the number, type, location and specifications of the controls, such as construction, padlocks, etc.	✓	✓		✓ (operations area only)
	Physical Barrier	**Perimeter of the site** must be surrounded by a physical barrier that prevents unauthorized access (s.74(b))			✓		
		Operations area must be surrounded by a physical barrier that prevents unauthorized access (s. 69)		✓			
		Storage area must be surrounded by a physical barrier that prevents unauthorized access (s.69, s.74(c) and s.75(a))		✓	✓	✓	

Requirement (Reference to Cannabis Regulations)			Examples of evidence to demonstrate how the requirement would be met	Standard Cultivation, Standard Processing and Sale for Medical Purposes (cannabis on site)	Micro-cultivation, Micro-processing and Nurseries	Analytical Testing	Research
	Location of Storage Areas	Each **storage area** must be located within an area that satisfies the security measures set out in subsection 68(1), section 69, subsections 70(1) and (3), subsection 71(1) and Section 72 (s. 67)	Area clearly shown on the site and floor plans	✓			
Access Control	Restricted Access	Access to each **operations area and storage area** must be restricted to individuals whose presence in the area is required by their duties (s.68(1), s.74(d) and s.75)	• Access control as well as details on the types, specifications, and locations of access control mechanisms installed and operating (e.g., card swipe, keypad code, combination lock, padlock, etc.) clearly marked and labelled with unique identifiers on security floor plans.	✓	✓ (storage area only)	✓ (storage area only)	
	Record of entry and exit	A record must be made of the identity of every individual entering or exiting a **storage area**. (s.68(2))	• Method used to record and the information it will capture. *Note that if this is not available at the time of application, an attestation must be provided and this information will be requested at a later time (i.e., with the site evidence package)*	✓			

Requirement (Reference to Cannabis Regulations)			Examples of evidence to demonstrate how the requirement would be met	Standard Cultivation, Standard Processing and Sale for Medical Purposes (cannabis on site)	Micro-cultivation, Micro-processing and Nurseries	Analytical Testing	Research
Monitoring and Recording	Visual Monitoring and Recording Devices	The perimeter of the site as well as each operations and storage area must be monitored at all times by visual recording devices to detect any attempted or actual unauthorized access to the site, or in the case of operations and storage areas, to detect illicit conduct. The devices must, in the conditions under which they are used, be capable of making a visible recording of any attempted or actual unauthorized access or in the case of operations and storage areas, of any illicit conduct. **For a grow area:** only the entry and exit points of the area must be visually monitored by such devices. (s.64 and s.70)	• The type and specifications of the visual monitoring devices and how the devices meet the requirements. • The type, number and location of visual monitoring devices installed.	✓			
	Intrusion Detection System	The perimeter of the site as well as each operations and storage area must be secured by means of an intrusion detection system that operates at all times and that allows for the detection of - any attempted or actual unauthorized access to the site; - any attempted or actual tampering with the system. And for **operations and storage areas (excluding grow areas)**, any unauthorized movement in the area (s. 65 and s.71)	• The type and specifications of the system installed for detection of access. • The type, number and location of devices installed for detection of movement. • Capabilities of the system installed to ensure that it can operate at all times and in all conditions (weather-proof; day/night capabilities, tamper-resistant, etc.).	✓			

Requirement (Reference to Cannabis Regulations)			Examples of evidence to demonstrate how the requirement would be met	Standard Cultivation, Standard Processing and Sale for Medical Purposes (cannabis on site)	Micro-cultivation, Micro-processing and Nurseries	Analytical Testing	Research
Monitoring and Recording	Monitoring and Response	The intrusion detection system must be monitored at all times. The holder of the licence must determine the appropriate measures to be taken in response to the detection of any occurrence. If any such occurrence is detected, the holder of the licence must ensure that a document is retained that contains the following information: (a) the date and time of the occurrence; and (b) the measures taken in response to it and the date and time when they were taken. (s.66 and s.72)	• Information on how the alarm equipment will be monitored continuously (24/7), either on-site or off-site (e.g., may be ULC-certified company).	✓			

*There are no physical security requirements for a sale for medical purposes licence without possession of cannabis.

Appendix E: Organizational Security Plan SOP Priority Areas

Health Canada has identified four priority security areas that all applicants and licence holders will be expected to address through SOPs. The number of SOPs required is at the discretion of the applicant, but all four priority areas below must be addressed. As part of its OSP the applicant is required to submit a list and short description of its SOPs, not the SOPs themselves.

Priority area 1: Security clearances and adverse information about employees

Risk areas and potential mitigation measures to consider:

- Detecting and responding to new adverse information received that could compromise an employee's security clearance
- Detecting and responding to adverse information received regarding a non-security-cleared employee that could compromise the organization's security

Priority area 2: Physical security

Risk areas and potential mitigation measures to consider:

- Staff arrival and entry to the facility (procedure for gate/door to open, etc.)
- Guest, vendor and contractor arrival and entry to the facility (including deliveries/pick up)
- Response procedures for any arrival and entry breaches
- Staff access to areas where cannabis is present, including vault/storage areas (procedure for passing access controls/intrusion detection)
- Guest, vendor and contractor access to areas where cannabis is present, including vault/storage areas (including deliveries/pick-up)
- Response procedures for any access control or intrusion detection breaches to areas where cannabis is present, including vault/storage areas
- Storage and retrieval of video monitoring footage
- Testing of all physical security features and response procedures (frequency, method, etc.)
- Steps and other security measures that will be taken to ensure the safekeeping of cannabis when being shipped, delivered and or transported
- Destruction method and handling of cannabis waste

Priority area 3: Security awareness and training

Risk areas and potential mitigation measures to consider:

- Internal security training and awareness requirements (for management and for employees)
- How employees can report security concerns, incidents or breaches

Priority area 4: Record keeping, reporting and testing

Risk areas and potential mitigation measures to consider:

- Contingency plan if record keeping system fails or goes down
- Detection of loss or theft
- Validation that cannabis entering the facility is from a legal source
- Protection of client information
- Response procedure should cannabis be found to enter or leave the facility in an unauthorized manner
- Testing of response procedures (frequency, method, etc.)

Appendix F: Good Production Practices Requirements

GPP requirements apply to a number of activities across many licence classes. Compliance with some requirements must be demonstrated as part of the application process. Compliance with others, or any of the GPP requirements may be verified at any time by Health Canada.

Regulatory GPP Requirement		**Examples of Evidence to demonstrate compliance plan**
SOPs	Cannabis must be produced, packaged, labelled, distributed, stored, sampled and tested in accordance with SOPs that are designed to ensure that those activities are conducted in accordance with the requirements of Part 5 of the *Cannabis Regulations*.	• A list of SOPs with detailed descriptions for each one and an attestation that they will be approved and signed/dated by the appropriate personnel. This should include SOPs on recall procedures. • A description of the training program for employees for each SOP, including training schedules and frequency.
Pest Control	Cannabis must not be treated with a pest control product unless the product is registered for use on cannabis under the *Pest Control Products Act* or is otherwise authorized for use under that Act.	• An attestation that any pesticides to be used will be registered under the Pest Control Products Act or will otherwise be authorized for use under the Act (e.g., those products that are exempt from the registration requirement). • A description of pest control management procedures, including any measures, such as controls and training, to mitigate the risk of the application of pesticides that are not registered or otherwise authorized for use on cannabis under the Act.
Storage	Cannabis must be stored under conditions that maintain its quality.	• Description of where, when and how cannabis will be stored (e.g. shelving, packaging, access to storage area, temperature/humidity tracking, etc.) and distributed (including transported, sent or delivered) to maintain its quality (e.g., shelving, packaging, access to storage area, environmental conditions).
Distribution	Cannabis must be distributed in a manner that maintains its quality.	

Regulatory GPP Requirement		Examples of Evidence to demonstrate compliance plan
		• Description/depiction of building showing the process flow through the building, separation of operations, storage areas and non-cannabis areas.
*Building or part of Building (*does not apply to outdoor cultivation, propagation, harvesting)*	Cannabis must be produced, packaged, labelled, stored, sampled and tested in a building that is designed, constructed and maintained in a manner that permits those activities to be conducted under sanitary conditions, and in particular that (a) permits the building or part of the building to be kept clean and orderly; (b) permits the effective cleaning of all surfaces in the building or part of the building; (c) prevents the contamination of cannabis; and (d) prevents the addition of an extraneous substance to the cannabis.	• Description/depiction of the building detailing: construction material (e.g., non-porous, non-shedding, cleanable), finishing materials, ability to clean and sanitize (as applicable) surfaces including ceilings, walls (e.g., non-porous panels, sealant etc.), floors (e.g., epoxy sealant), seams (e.g., caulking, joints between floor, walls, and ceiling).
*Filtration of air (*does not apply to outdoor cultivation, propagation, harvesting)*	The building or part of the building where cannabis is produced, packaged, labelled and stored must be equipped with a system that filters air to prevent the escape of odours.	• Description of the air filtration system, including type, specifications, number and location of air filters installed (e.g., HEPA, carbon, charcoal, combination, portable filters) and a diagram/ floor plan detailing the air filtration/ventilation system (e.g., air intake and air exhaust locations).
Equipment	Cannabis must be produced, packaged, labelled, stored, sampled and tested using equipment that is designed, constructed, maintained, operated and arranged in a manner that (a) permits the effective cleaning of its surfaces; (b) permits it to function in accordance with its intended use; (c) prevents the contamination of the cannabis; and (d) prevents the addition of an extraneous substance to the cannabis **(with the exception of outdoor cultivation, propagation,**	• Description of the type of equipment to be used (e.g., stainless steel, food grade), and the construction of the equipment (i.e., to demonstrate it is easy to clean, rustproof, will not shed particles, can withstand repeated cleaning etc.), calibration of equipment to function as intended, and cleaning/replacement/preventative maintenance program for equipment.

Regulatory GPP Requirement		Examples of Evidence to demonstrate compliance plan
	harvesting)	
Sanitation Program	Cannabis must be produced, packaged, labelled, stored, sampled and tested in accordance with a sanitation program that sets out (a) procedures for effectively cleaning the building or part of the building in which those activities are conducted (does not apply to outdoor cultivation); (b) procedures for effectively cleaning the equipment used in those activities; (c) procedures for handling any substance used in those activities; and (d) all requirements, in respect of the health and hygienic behaviour of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.	• Description of how areas where activities with cannabis are conducted will be cleaned, considering transitory areas (e.g., hallways, holding areas, etc.). • Training plans/schedules for staff on handling substances and other procedures with cannabis. • A description of how health and hygienic behaviour will be maintained (e.g., managing communicable diseases and cuts; eating/drinking policies; handwashing practices; showering; personal protective equipment (PPE) such as clothing, gloves, hair nets, protective glasses and boots; etc.). • How equipment will be installed. • Frequency of equipment cleaning. • What products will be used for cleaning.
Quality assurance (for processing licence only)	Every complaint received in respect of the quality of the cannabis must be investigated by the QAP who must, if necessary, take corrective and preventative measures.	• Description of how methods and procedures, as well as how lots and batches of cannabis prior to sale will be approved by the QAP. • Description of how the QAP will investigate complaints.
Methods and Procedures (for processing licence only)	The cannabis must be produced, packaged, labelled, distributed, stored, sampled and tested using methods and procedures that, prior to their implementation, have been approved by a QAP.	
Approval Prior to Sale (for processing licence only)	Every lot or batch of cannabis must be approved by a QAP before it is made available for sale.	
Testing	Must be conducted using validated methods. Must be conducted on each lot or batch of cannabis and include a number of testing requirements depending on the cannabis product	• Name of testing laboratory to be provided and attestation that validated methods will be used.

Regulatory GPP Requirement		Examples of Evidence to demonstrate compliance plan
	class as further outlined in the Regulations. In addition, a portion of the sample must be kept for at least one year after the date of the last sale of any portion of the lot or batch and must be of sufficient quantity to enable a determination of whether the lot or batch meets the requirements outlined in the Regulations.	

Appendix G: Licensing Record Keeping Information Requirements

The following record keeping requirements must be demonstrated in the application:

- How cannabis is tracked from the time it enters the facility to when it leaves the facility.
- Communications sent to local authorities.
- Inventory and distribution records for all cannabis that is possessed by the licence holder, including:
    - dates when activities occurred, including packaging, and quantities of cannabis involved
    - receipt of cannabis
    - sale, distribution and export of cannabis and transfer of cannabis
- Information regarding destruction methods and activities including compliance with the Regulations in that it:
    - complies with all federal, provincial and municipal environmental legislation applicable to the location at which it is to be destroyed
    - does not result in any individual being exposed to cannabis smoke or cannabis vapour
    - that two (2) qualified individuals are present to witness destruction and, except in the case of analytical testing or research, one of whom holds a security clearance and is an employee of the licence holder
- Records relating to physical and personnel security, including the OSP
- Records required to demonstrate compliance with required GPP, including:
    - documents demonstrating that each lot or batch met GPP requirements
    - copies of SOPs and the sanitation program
    - qualifications of the QAP
- Copies of complaints received, investigations undertaken and resulting corrective actions
    - Information respecting the system or controls established to enable recall of cannabis as well as information for any recalls that have occurred
    - Information respecting promotional activities
    - Information respecting research and development undertaken, including information such as the purpose and description of the research activity, the type and amount of cannabis substance used, and the product or compound produced as a result; and copies of import and export declarations and permits.

Please review the regulations for the post licensing record keeping and reporting requirements.

Appendix H: CTLS Application Status

An applicant may check the status of their application in the CTLS at any time during the application process. The table below provides an explanation of what the status means.

Status	Explanation
Draft	The application has not yet been submitted by the applicant. Health Canada does not receive, nor process, draft applications. The applicant must complete all sections of the application in order to submit an application for processing by Health Canada.
Payment (Pending)	*Information on cost recovery fees will be provided by Health Canada, when applicable.* The applicant has submitted the application but required payment for the processing of the application, if applicable, has not yet been processed.
Submitted	Once the payment, if applicable, is received by Health Canada, the application is considered 'submitted' and remains at this stage until the screening of the application commences.
In progress	Health Canada has begun review of the application. Refer to section 7.2 of this guide for more information.
Pending information	A request for more information has been sent and Health Canada is waiting for a response from the applicant. Refer to 7.3.1 of this guide for more information.

Appendix I: Key Investors

The Regulations provide the complete definition of a key investor. In essence, a key investor is a person who exercises, or is in a position to exercise, direct or indirect control over the licence holder. When the term "in a position to exercise, direct or indirect control over the holder" is used, an individual, partnership, cooperative or corporation will be considered to be controlled by another individual or organization at any time where, at that time, the controller has any direct or indirect influence that, if exercised, would result in control in fact of the individual, partnership, cooperative or corporation.

As part of the licensing application, any person (except a corporation who trades its shares on a public market) who applies for a cultivation, processing or sale for medical purposes licence must provide certain information regarding key investors, such as the key investor's name and mailing address; a description of the means by which the key investor exercises, or is in a position to exercise, control over the holder and, if known, whether the controlling interest has been, will be, or could be assigned, pledged, mortgaged, hypothecated or sold, in whole or in part, to any person.

A person may have control in fact of an organization even though that person does not have legal control of the organization. Legal or direct control of an organization generally entails the right to elect the majority of the board of directors based on having a sufficient number of voting shares.

Control in fact includes the ability to control by any direct or indirect influence, and it may exist even without the ownership of any shares. It can take many forms such as the ability of a person to: change the board of directors or reverse its decisions; make alternative decisions concerning the actions of the organization in the short, medium or long term; directly or indirectly terminate the organization or its activities; or to appropriate its profits and property. The existence of such influence, even if it is not actually exercised, would be sufficient to result in control in fact.

In order to determine whether an investor has control in fact, and whether information about this investor needs to be reported, the following are some of the relevant general factors to consider:

- the percentage of ownership of voting shares (when such ownership is not more than 50 per cent) in relation to the holdings of other shareholders – although any ownership over 25 per cent, in combination with other factors would likely be a significant indication of control
- ownership of a large debt of an organization which may become payable on demand
- shareholder agreements including the holding of a casting vote
- commercial or contractual relationships of the organization, e.g., economic dependence on a single supplier or customer.

Appendix J: Direct Control

In some instances, a partnership, cooperative or corporation that holds a licence can be controlled by an individual or another partnership, cooperative or corporation. The Regulations require that individuals, or directors and officers of cooperatives or corporations, must hold a valid security clearance when they directly control any partnership, corporation or cooperative that holds a cultivator, processor or sale for medical purposes licence.

With respect to partnerships, the terms of the partnership agreement will dictate who has control. Anyone who directly controls a partnership needs to hold a valid security clearance – this includes any individual, or if it is another partnership –those partners, and if a corporation or a cooperative – then its directors and officers.

Cooperatives and corporations can also be controlled by others –individuals, partnership, cooperative or a corporation. In common language, when this kind of control is exerted by a corporation, it is often referred to as a "parent company", which is a company that is able to control another company's management and operations by influencing or electing its board of directors, among other things. The *Cannabis Regulations* require the directors and officers of any parent company/cooperative, which is a corporation or cooperative that has significant ownership over a subsidiary or group of subsidiaries, to hold security clearances. These partially or wholly owned companies or cooperatives are controlled by the parent, to varying degrees; however, all parent companies, for the most part, own more than 50% of a subsidiary's voting stock. This applies to any individual or partnership that owns more than 50% of a subsidiary's voting stock.

If an individual controls any of the above licence holders by holding an influential amount of voting stock or through the terms of a partnership agreement, they would require a security clearance.

Appendix K: Security Clearance – Consent and Certification Form

Providing misleading or false information on this application may result in a refusal or cancellation of the security clearance.

For security clearance purposes, I consent to the disclosure by the Royal Canadian Mounted Police (RCMP) to other law enforcement agencies, of any and all information provided by me in support of this application. Without limiting the generality of the foregoing, this includes information relating to my date of birth, education, residential history, employment history, and immigration and citizenship status in Canada. I also consent to the disclosure and use of my fingerprints and facial images for identification purposes.

I consent to the disclosure by law enforcement agencies to Health Canada and/or the RCMP of any and all information relevant to this security clearance application, including information in my criminal record and any other information contained in law enforcement records, including information gathered for law enforcement purposes, as well as any and all information that will facilitate the conduct of a security assessment. This includes non-conviction information, charges before the courts, findings of guilt or convictions and court orders registered in my name in the National Repository of Criminal Records and local records available to police services.

For security clearance purposes, I hereby authorize Health Canada to seek, verify, assess, collect, and retain for a period of two (2) years after the expiry date of the licence holder's licence, any and all information relevant to this application including any criminal records and any and all information contained in law enforcement files, including intelligence gathered for law enforcement purposes, and information with respect to my immigration and citizenship status, as well as any and all information that will facilitate the conduct of a security assessment. This includes non-conviction information, charges before the courts, findings of guilt or convictions and court orders registered in my name in the National Repository of Criminal Records and local records available to police services.

For security clearance purposes only, I consent to the release by other Canadian institutions or agencies to Health Canada, of information relevant to this application for a security clearance to enable Health Canada to perform security screening assessments in order to determine whether a security clearance should be granted to me.

This consent is given solely for security clearance purposes. Unless cancelled in writing by me and notification is given in writing to Health Canada, this consent shall remain valid for conducting all the necessary verifications, specified checks, assessments and/or investigations, including any subsequent required verifications, if need be, as well as any requirements for updates.

I certify that all the information set out by me in this application for a security clearance, including any supporting documentation, is true and correct to the best of my knowledge and belief.

_____

Applicant's Name (print in block letters)

_____ _____

Applicant's Signature Date (YYYY/MM/DD)

_____ _____

Home telephone Work telephone

Privacy Notice Statement

The personal information you provide on this form to Health Canada is governed in accordance with the *Privacy Act*. This Notice explains the purposes of the collection and use of the personal information you provide on this form. We only collect the information required for a security clearance as part of the application pursuant to the *Cannabis Regulations*. Security clearance is a requirement under the *Cannabis Regulations* for issuance of a licence. A refusal to provide the information requested on this form will result in a refusal to process the application. The personal information collected by Health Canada will be used to process the application. The personal information collected by Health Canada will also be disclosed to the Royal Canadian Mounted Police (RCMP) for the purpose of conducting a criminal record check and a check of the relevant files of other law enforcement agencies, including intelligence gathered for law enforcement purposes. In some cases, personal information may be disclosed without your consent for purposes not outlined here pursuant to subsection 8 (2) of the *Privacy Act*. A Personal Information Bank (PIB) is under development and will be included in infosource.gc.ca. You have the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy

Management Division at 613-946-3179 or HC.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.